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Pamela J. Sherwood, Ph.D.
BOZICEVIC, FIELD & FRANCIS, LLP
1900 University Avenue, Suite 200
East Palo Alto, CA 94303

In re Application of :
Berg :Decision on Petition
Serial No.: 10/716,349 :
Filed : 17 November 2003 :
Attorney Docket No.: SEEK-001CON :

This letter is in response to the Petition filed on 9 April 2008 to requests review of the restriction requirement.

BACKGROUND

This application was filed under 35 USC 111(a) and as such is eligible for US restriction practice under 35 USC 121 and chapter 800 of the MPEP.

On 23 June 2006, the examiner required an election of species between
Species A (claim 18) wherein the test cell culture and the control cell culture comprise at least two different cell types or
Species B, (Claim 19) wherein the cell are primary cells.

Claims 17 and 20-22 were indicated as generic.

On 24 July 2006, applicants elected Species B, primary cells without traverse.

On 24 October 2007, the examiner withdrew claim 18 from consideration and rejected claim 17 under 35 USC 112, 2nd paragraph, claims 17 and 19-22 under 35 USC 102(e) as being anticipated by Friend et al., and rejected claims 17 and 19-22 under nonstatutory double patenting.

On 23 April 2007 Applicants responded to the Office action and by the addition of new claim 23.

On 26 June 2007, the examiner mailed a Final Office action in which claims 18 and 23 were withdrawn from consideration as being directed to non-elected inventions. Claim 18 is directed to non-elected Species A. Claim 23 was considered distinct from the originally presented claims. Claims 17 and 19-22 were rejected under 35 USC 102(e) and nonstatutory double patenting.

On 26 October 2007, applicants filed a request for continued examination.

On 22 October 2007, the examiner mailed an Office action in which claims 18 and 23 were withdrawn from consideration as being directed to non-elected inventions. Claim 18 is directed to non-elected Species A. Claim 23 was considered distinct from the originally presented claims. Claims 17 and 19-22 were rejected under 35 USC 102(e) and nonstatutory double patenting.

This petition was filed on 9 April 2008.

DISCUSSION

This file history and petition have been carefully considered.

The petition requests rejoinder of Claims 18 and 23. Each claim will be treated in turn.

Claim 18 is directed to non-elected species (A). In order to preserve the right to petition under 37 CFR 1.144, applicants must elect with traverse.

37 CFR 1.144. Petition from requirement for restriction.

After a final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may petition the Director to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested (see § 1.181). (Emphasis added)

It is noted that applicant elected Species (B) without traverse in the papers filed 24 July 2006, so this petition decision will not address the election of species required between claim 18 and 19 in the original restriction requirement.

Moreover, request for rejoinder of Claim 18 is premature, given the fact that the generic claims 17 and 20-22 are currently not in condition for allowance. Per MPEP 821.04,

The propriety of a restriction requirement should be reconsidered when all the claims directed to the elected invention are in condition for allowance, and the nonelected invention(s) should be considered for rejoinder. Rejoinder involves withdrawal of a restriction requirement between an allowable elected invention and a nonelected invention and examination of the formerly nonelected invention on the merits.

In order to be eligible for rejoinder, a claim to a nonelected invention must depend from or otherwise require all the limitations of an allowable claim. (Emphasis added)

For these two reasons, the withdrawal of claim 18 from examination is considered proper.

Turning now to Claim 23, it was not pending at time of restriction requirement. Claim 23 was added after the first Office action on the merits. 37 CFR 1.145 addresses the treatment of subsequently presented of claims for different invention:

If, after an office action on an application, the applicant presents claims directed to an invention distinct from and independent of the invention previously claimed, the applicant will be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in § § 1.143 and 1.144

Claim 17 and 23 are compared as follows:

Claim 17. A method for analyzing a candidate compound for a biological activity of interest, the method comprising	Claim 23. A method for characterization of a biologically active agent, the method comprising
contacting a test mammalian cell culture with said compound, wherein said culture comprises a plurality of factors wherein a plurality of signaling pathways are induced by the presence of the factors	contacting said agent with human primary cells in at least one cell culture assay combination comprising at least two factors acting on said cells
measuring at least two parameters associated with said plurality of pathways and comparing the measurement of said at least two parameters with the measurement from a control cell culture lacking said compound, and	recording changes in at least three different cellular parameter readouts as a result of introduction of said agent
recording said measurements of said test cell culture and said control cell culture to produce a biological dataset profile, wherein said biological dataset profile is indicative of the pathways that are active in said culture cells.	deriving a biomap from said changes in parameter readouts, wherein said biomap comprises data normalized to be a ratio of test to control data on the same cell type under control conditions in the absence of said biologically active agent, and said parameters are optimized so that the set of data in the biomap is sufficiently informative that it can discriminate the mechanism of action of said agent
	analyzing said biomap by a multiparameter pattern recognition algorithm to qualify the relatedness of said biomap to reference biomaps that include known agents that target specific pathways, wherein the presence or absence of relatedness to said reference biomaps provides a characterization of said agent.

To establish distinction between Claim 17 and 23:

Claim 17 and Claim 23 are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed each require a characteristic not required for the other method. For example, Claim 17 requires signaling pathways which are not required for Claim 23. Claim 23 requires parameters that are optimized so that the set of data in the biomap is sufficiently informative that it can discriminate the mechanism of action of said agent, which is not required for claim 17. Moreover, Claim 17 results in information about the pathways which are active in the culture. Claim 23 results in information concerning the characterization of the agent. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants

To establish burden:

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicants comments concerning claims filed in copending applicants are considered immaterial.

DECISION

For these reasons, the petition is **DENIED**.

Applicants remain under obligation to respond to the Office action mailed 22 October 2007 within the time period set therein or extendable under 37 CFR 1.136(a).

Any request for reconsideration must be filed within TWO MONTHS of the mailing date for this action.

Should there be any questions regarding this decision, please Quality Assurance Specialist/Program Manager Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 571-273-8300.



John LeGuyader
Director, Technology Center 1600